We Claim:

1. A device for compacting cancellous bone comprising a wall made from an elastomer material and including a region preformed with a normally expanded shape outside bone.

2. A device according to claim 1

wherein the wall includes a second region, spaced from the first-defined region, and preformed with a normally expanded shape outside bone.

3. A device according to claim 2

wherein the first-defined region and the second regions, when further expanded beyond their respective normally expanded shapes to reach a given inflation volume, present a maximum diameter less than a sphere expanded to an equal inflation volume.

4. A device according to claim 2

wherein the wall includes a third region, preformed with a normally expanded shape outside bone, and positioned between the first-defined region and the second region.

5. A device according to claim 4

wherein the first-defined region, the second region, and the third region, when expanded beyond their respective normally expanded shapes to reach a given inflation volume, present a maximum diameter less than a sphere expanded to an equal inflation volume.

6. A device according to claim 1

wherein the expandable region has non-uniform wall thickness.

7. A device according to claim 1

wherein the expandable region includes a further expanded shape, outside bone, having a diameter greater than the normally expanded shape.

8. A device according to claim 7

wherein the expandable region has a further

expanded shape inside bone that substantially corresponds to the further expanded shape outside bone.

9. A device according to claim 1

wherein the elastomer material has an ultimate elongation of greater than about 300%.

10. A device according to claim 1

wherein the elastomer material includes polyurethane.

11. A device according to claim 1

wherein the elastomer material is resistant to abrasion by cancellous bone.

12. A device according to claim 1

wherein the elastomer material possesses a Taber abrasion resistance value of less than about 90 mg loss for resistance to abrasion by cancellous bone.

13. A device according to claim 1

wherein the elastomer material possesses a rotating drum abrasion resistance value of less than about 70 mm^3 for resistance to abrasion by cancellous bone.

14. A device according to claim 1

wherein the elastomer material possesses a tear strength value of greater than about 280 lbf/in for resistance to abrasion by cancellous bone.

15. A device according to claim 1

wherein the elastomer material possesses a Shore hardness value of less than about 100 A for elastomeric expansion within and resistance to abrasion by cancellous bone.

16. A device according to claim 1

wherein the elastomer material possesses a softening temperature greater than about 50° C.

17. A device for compacting cancellous bone comprising a body having a first diameter, and an expandable region formed from the body with a shape having, outside bone, a normally expanded diameter greater than the first

diameter, and a further expanded shape having a diameter, outside bone, greater than the normally expanded diameter, the further expanded shape inside bone substantially corresponding with the further expanded shape outside bone.

18. A device according to claim 17

wherein the body has a first wall thickness, and wherein the expandable region has a wall thickness less than the first wall thickness.

19. A device according to claim 17

wherein the normally expanded diameter is at least about 5% greater than the first diameter.

20. A device according to claim 17

wherein the expandable region includes an elastomer material.

21. A device according to claim 20

where the elastomer material includes polyurethane.

22. A device according to claim 17

wherein the expandable region includes material that is resistant to abrasion by cancellous bone.

23. A device for compacting cancellous bone comprising a wall including a region preformed to possess a normally expanded shape outside bone, which is further expandable to an enlarged shape outside bone at substantially constant pressure.

24. A device according to claim 23

wherein the region is expandable to an enlarged shape inside bone at substantially constant pressure having a magnitude determined by resistance of cancellous bone to compaction.

25. A device according to claim 23

wherein the region has an enlarged shape, when expanded inside bone, which substantially conforms to the enlarged shape outside bone.

26. A device according to claim 23

wherein the region includes an elastomer material.

27. A device according to claim 26

wherein the elastomer material includes polyurethane.

28. A device according to claim 23

wherein the region includes material that is resistant to abrasion by cancellous bone.

29. A device for compacting cancellous bone comprising an expandable wall including material that is resistant to abrasion by cancellous bone.

30. A device for compacting cancellous bone comprising an expandable wall and a material covering the expandable wall that is resistant to abrasion by cancellous bone.

31. A device according to claim 29 or 30

wherein the material includes polyurethane material.

32. A device according to claim 29 or 30

wherein the material includes elastomer material.

33. A device according to claim 29 or 30

wherein the material possesses a rotating drum abrasion resistance value of less than about 70 mm^3.

34. A device according to claim 29 or 30

wherein the material has an abrasion resistance value of less than about 90 mg loss.

35. A device according to claim 29 or 30

wherein the material has a tear strength value of greater than about 280 lbf/in.

36. A device according to claim 29 or 30

wherein the material has a durometer of shore hardness less than about 100 A.

37. A device for compacting cancellous bone comprising a tube made of an elastomer material, the tube including a first section having a first diameter and a second section preformed by heat and pressure to a second

PCT/US95/09960

normally expanded diameter, which is greater than the first diameter, the second section having a further expanded shape with a third diameter greater than the second normally expanded diameter.

38. A device according to claim 37

wherein the elastomer material includes polyurethane.

39. A device according to claim 37

and further including a conduit to convey fluid to the tube to expand the second section from the second normally expanded diameter to the further expanded shape at a substantially constant pressure.

40. A device according to claim 37

wherein the normally expanded diameter is at least 5% greater than the first diameter.

41. A device according to claim 37

wherein the elastomer material has an ultimate elongation of greater than about 300%.

42. A device according to claim 37

wherein the elastomer material has a softening temperature greater than about 50° C.

43. A device according to claim 37

wherein the first section has a first wall thickness, and

the second section has a second wall thickness different than the first wall thickness.

44. A device according to claim 43

wherein the second wall thickness is less than the first wall thickness.

45. A system for compacting cancellous bone comprising

a device as defined in claim 1 or 23 or 29 or 30 or 37, and

instructions for using the device according to a method comprising the step of expanding the device inside

bone to compact cancellous bone and form a cavity.

46. A system according to claim 45 wherein the method for use further includes the step of filling the cavity with material.

47. A system according to claim 46 wherein the method for use further includes the step of removing the device from bone prior to the filling step.

48. A system according to claim 46 wherein the material comprises bone cement.

49. A system according to claim 46 wherein the material comprises synthetic bone substitute.

50. A system according to claim 46 wherein the material comprises a flowable material that sets to a hardened condition.

51. A system according to claim 46 wherein the material comprises allograft tissue.

52. A system according to claim 46 wherein the material comprises autograft tissue.

53. A system according to claim 46 wherein the material comprises medication.

54. A device for insertion into a vertebral body having a top plate and a bottom plate, the device including an expandable wall that, when expanded inside the vertebral body, moves at least one of the top and bottom plates, the improvement comprising the expandable wall being made from an elastomer material and including a region preformed with a normally expanded shape outside bone.

55. A device according to claim 54 wherein the elastomer material includes polyurethane.

56. A device according to claim 54 wherein the wall includes a second region, spaced from the first-defined region, and preformed with a normally

expanded shape outside bone.

57. A device according to claim 56

wherein the first-defined region and the second regions, when further expanded beyond their respective normally expanded shapes to reach a given inflation volume, present a maximum diameter less than a sphere expanded to an equal inflation volume.

58. A device according to claim 56

wherein the wall includes a third region, preformed with a normally expanded shaped outside bone, and positioned between the first-defined region and the second region.

59. A device according to claim 58

wherein the first-defined region, the second region, and the third region, when expanded beyond their respective normally expanded shapes to reach a given inflation volume, present a maximum diameter less than a sphere expanded to an equal inflation volume.

60. A device according to claim 54

wherein the expandable region includes a further expanded shape, outside bone, having a diameter greater than the normally expanded shape.

61. A device according to claim 60

wherein the expandable region has a further expanded shape inside bone that substantially corresponds to the further expanded shape outside bone.

62. A device according to claim 54

wherein the elastomer material has an ultimate elongation of greater than about 300%.

63. A device according to claim 54

wherein the elastomer material is resistant to abrasion by cancellous bone.

64. A method for compacting cancellous bone comprising the steps of

introducing into bone a device including an

expandable wall made from an elastomer material and including a region preformed with a normally expanded shape outside bone, and

expanding the wall inside bone from the normally expanded shape to a further expanded shape to compact cancellous bone and form a cavity.

65. A method according to claim 64 and further including the step of filling the cavity with a material.

66. A method according to claim 65 and further including the step of removing the device from bone prior to the filling step.

67. A method according to claim 65

wherein the material comprises bone cement.

68. A method according to claim 65

wherein the material comprises synthetic bone substitute.

69. A method according to claim 65

wherein the material comprises a flowable material that sets to a hardened condition.

70. A method according to claim 65

wherein the material comprises allograft tissue.

71. A method according to claim 65

wherein the material comprises autograft tissue.

72. A method according to claim 65

wherein the material comprises medication.

73. A method for treating a vertebral body having a top plate and a bottom plate comprising the steps of

inserting into the vertebral body between the top and bottom plates a device comprising an expandable wall made from an elastomer material and including a region preformed with a normally expanded shape outside bone, and

expanding the wall inside bone from the normally expanded shape to a further expanded shape to move at least one of the top and bottom plates.

74. A method for manufacturing a device for compacting cancellous bone comprising the step of applying heat and pressure to a tube of an elastomer material to form a region having a normally expanded shape outside bone, which is expandable to a further expanded shape outside bone having a diameter greater than the normally expanded shape.

75. A method according to claim 74
wherein the elastomer material is resistant to abrasion by cancellous bone.

76. A method according to claim 74
wherein the elastomer material has a softening temperature greater than about 50° C.

77. A method according to claim 74
wherein the elastomer material has an ultimate elongation value of greater than about 300%.

78. A method according to claim 74
wherein the elastomer material possesses a tear strength value of greater than about 280 lbf/in for resistance to abrasion by cancellous bone.

79. A method according to claim 74
wherein the elastomer material possesses a Shore hardness value of less than about 100 A for elastomeric expansion within and resistance to abrasion by cancellous bone.

09837350.021401

INS A1

A1

add B5